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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,283	05/04/2006	Tetsuji Yamaoka	18900-004US1 200640/US	2757
26211	7590	03/03/2011	EXAMINER	
FISH & RICHARDSON P.C. (NY) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				POPA, ILEANA
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE			DELIVERY MODE	
03/03/2011			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/578,283	YAMAOKA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 July 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 04 May 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>08/03/2006;05/04/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of  $-\text{COONH}\text{-(CH}_2\text{)}_{n_y}\text{-}$  as the Y species,  $\text{NNR}_3\text{R}_4$  as the Z species,  $-\text{OC(=O)-R}_c\text{-C-OZ}^1$  as the X species, and  $-\text{C(=O)O-}$  as the W species, in the reply filed on 07/22/2008 is acknowledged.

Upon further considerations, the species election requirement is hereby withdrawn.

Claims 5-10 have been amended.

Claims 1-11 are pending and under examination.

### ***Priority***

2. It is acknowledged that certified copies of the foreign priority papers have been received. However, an English translation has not been provided.

Should Applicants provide a certified translation of their foreign priority document to overcome the prior art rejection, Applicants should indicate whether the priority application is identical to the instant application, or if the priority application contains additional disclosure. If there is additional disclosure, a brief summary should be provided. Applicants should also indicate where support for each of the claim limitations (for the independent claims) can be found in the translated priority document by page and line number. If support is not found *in ipsis verbis*, clarification on the record may be helpful to the examination process.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurisawa et al. (J Control Release, 2000, 68: 1-8), in view of Fajac et al. (Glycoconjugate Journal, 2001, 18: 723-729) and Aoyagi et al. (J Biomater Sci Polymer Edn, 2000, 11: 101-110).

Kurisawa et al. teach a method of introducing a DNA into cells by administering to the cells a complex between the DNA and a carrier, wherein the carrier is a copolymer comprising 2-(dimethylamino)ethyl metacrylate (i.e., a cationic repeating unit having a structure according to formula I wherein  $n_\gamma$  is 2), N-isopropylacrylamide, and butylmetacrylate (i.e., a hydrophobic repeating unit having a structure according to formula V) (claims 1, 2, 6, 9, and 10) (Abstract; p. 2, paragraph bridging columns 1 and 2 and column 2, first full paragraph; p. 3, column 3; p. 7, column 1). Kurisawa et al. teach their carrier as having a ratio of 2-(dimethylamino)ethyl metacrylate + N-isopropylacrylamide to butylmetacrylate of 98:2 (claim 7) and a molecular weight of 40,000 to 200,000 (claim 8) (p. 4, column 1, first full paragraph and Table 1).

Kurisawa et al. do not teach a saccharified copolymer (claims 1 and 11). However, using a saccharified copolymer is suggested by the prior art. For example, Fajac et al. teach cell-specific DNA delivery by using glycosylated carriers capable of

binding lectins expressed by the cell of interest (Abstract; p.724, column 1). It would have been obvious to one of skill in the art, at the time the invention was made, to glycosylate the carrier of Kurisawa et al. by using N-isopropylacrylamide derivatized with sugars, with a reasonable expectation of success. One of skill in the art would have been motivated to do such in order to obtain a carrier for specific delivery to target cells. One of skill in the art would have reasonably expected to be successful in doing so because the prior art teaches that reactive groups can be successfully introduced into N-isopropylacrylamide (see Aoyagi et al., Abstract). With respect to the recited formulae II-IV (claims 3-5), there is no evidence on the record that using monomers having the claimed formulae results in a carrier exhibiting an unexpected property. The specific monomers are not significant if they do not provide a novel feature.

Thus, the claimed invention was *prima facie* obvious at the time it was made.

5. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/  
Primary Examiner, Art Unit 1633